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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,880	10/22/2003	Nancy M. Lee	056367-2051	8369

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EXAMINER	
SCHLAPKOHL, WALTER	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/690,880	LEE ET AL.	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	waf

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-95* is/are pending in the application.

4a) Of the above claim(s) *1-48,50,65-78,80 and 89-95* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49,51-64,79 and 81-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/6/06 & 6/7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the papers filed 6/21/2006 in which claims 52 and 84 were amended. Claims 1-95 are pending. Claims 1-48, 50, 65-78, 80 and 89-95 are withdrawn. Claims 49, 51-64, 79, and 81-88 are under examination in the instant Office action.

Election/Restrictions

Claims 1-48, 50, 65-78, 80 and 89-95 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/21/2006.

Applicant's election with traverse of Group III (claims 49-64) in the reply filed on 6/21/2006 is acknowledged. The traversal is on the ground(s) that at least the Group III and Group V (claims 79-88) inventions should be rejoined because the kits of Group V include the compositions recited within claims 49-64 (Group III). Furthermore, Applicant argues that restriction of the kits of Group V away from the methods comprising the nucleotides included in the kits would run the

risk of burdening the USPTO with unnecessary examination. Applicant's arguments have been found persuasive in part because Applicant has elected the identical combination of SEQ ID NOs: for the Group V invention as for the elected Group III invention. As a result, the search requirement among the Group III and Group V inventions is no longer burdensome and Examiner has agreed to rejoin Groups III and V ONLY.

The requirement is still deemed proper and is therefore made FINAL.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Specifically, Applicant has made a non-initial change to the address listed for Nancy M. Lee. This change is inconsistent with the Application Data Sheet (ADS) submitted prior to submission of the declaration. In cases where the ADS and the declaration are inconsistent, it is the later-filed document which governs except in the naming of inventors and in

the setting forth of the inventor(s)' citizenship (CFR 1.76(d)). In the instant case, the declaration is the later-filed document and therefore governs.

Priority

Applicant's claim for the benefit of priority to provisional application 60/488,660, submitted 7/18/2003, is acknowledged. However, application 60/488,660 does not disclose polynucleotide sequences for any of the claimed polynucleotides or primers recited in the instant claims. Furthermore, application 60/488,660 does not disclose the use of an SAA1 gene in a biomarker panel for colorectal cancer or colorectal polyps. Therefore, priority for the claimed invention is granted only as far back as the filing date of the instant application: 10/22/2003.

Claim Objections

Claims 49, 51-64, 79 and 81-88 are objected to because of the following informalities: the claims comprise non-elected subject matter (SEQ ID NOs: 3-4, 17-22, 49-52, 56-72 and 77-88). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61 & 85, and therefore dependent claim 62, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "minimally invasive" in claim 61 is a relative term which renders the claim indefinite. The term "minimally invasive" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For example, does a "minimally invasive step include a superficial scrape, a painless biopsy or only swabs and stool sample collection?

Claim 85 recites "[t]he kit of claim 84, further comprising reagents for the preparation of cDNA" in lines 1-2. Claim 85 is vague and indefinite in that it is unclear whether Applicant intends that the primers recited are intended for used in the analysis of polynucleotides but not as reagents for the

preparation of cDNA, or whether Applicant intends that the primers are used for both analysis of polynucleotides as well as reagents for the preparation of cDNA.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49, 51-64, 79, and 81-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to methods for measuring expression levels of polynucleotides from biomarkers for colorectal cancer and colorectal polyps comprising the selection of a panel of biomarkers comprising SEQ ID NOs: 1, 2, 5, 15 and 16. The expression levels are quantified using cDNAs amplified with primers of SEQ ID NOs: 45-48, 53-54 and 73-76. Some claims are further limited to such methods wherein the expression

levels of the biomarkers are compared to a control. Some claims are further limited to such methods wherein the comparison is used for the management of patient care (claims 57-58) or wherein the comparison is used for the discovery of therapeutic interventions of colorectal cancer and colorectal polyps (claim 59). Some claims are further drawn to such methods wherein the step of obtaining a sample of colorectal cells in minimally invasive. The claims encompass the use of any biological sample compared to any control. The claims do not provide any structural information with regard to the biological samples and controls which can be used such that patient care management, discovery of intervention and/or determination of colorectal cancer and colorectal polyps is acheived. Thus, the rejected claims comprise a set of biological samples and controls that are defined by their function.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and any combination thereof. The specification describes the use of a mouse multiple intestinal neoplasia (MIN)

model to determine expression differences between mouse MIN subjects comprising a chemically induced mutation in the APC gene and normal control littermates for which there was not aberration of the APC gene (page 5, paragraph 18). From these studies candidate genes were selected for study in human subjects; and from these studies with human samples, the disclosed panel of biomarkers was obtained (ibid). In one disclosed example, a panel of six biomarkers is applied to "biopsy samples" obtained from patients known to have CRC and from individuals independently validated as normal controls (page 8, paragraph 27). In another example, multiple "biopsy samples" taken from one exemplary patient diagnosed with CRC showed differences in expression of three biomarkers (see paragraph bridging pages 9 and 10). In the last example, the specification teaches that multiple biopsies (again from a single patient), taken over a 53 cm region of the colon, were able to "distinguish differences in the colon tissue for the patient," whereas the same biopsy samples were rendered normal by conventional histological analysis (page 10, paragraph 32). The specification also teaches that samples can be obtained by "minimally invasive swabbing" or collection of a stool sample (ibid). However, the specification does not teach which samples should be compared to which controls such that patient care is

managed, therapeutic interventions are discovered, or CRC or colorectal polyps are detected.

Even if one accepts that the examples described in the specification meet the claim limitations of the rejected claims with regard to structure and function, the examples are only representative of one nucleic acid sequence capable of biopsy samples from patients known to have colorectal cancer and verified "normal" counterparts. The results are not necessarily predictive of any other biological sample or control that can be used in methods for management of colorectal cancer or colorectal polyps or discovery of therapeutic interventions therefor. Thus it is impossible to extrapolate from the examples described herein those biological samples and controls that would necessarily meet the structural/functional characteristics of the rejected claims.

The prior art does not appear to offset the deficiencies of the instant specification in that it does not describe a set of biological samples and controls that can be used such that gene expression levels of SEQ ID NOs: 1, 2, 5, 15 and 16 dictate how patient care of patients with CRC or colorectal polyps should be managed. In post-filing art, Barrier et al (*Oncogene* 24:6155-6164, 2005; IDS Ref) teach the attempted construction of a prognosis predictor model for stage II and stage III colon

cancer based on gene expression measurements "from tumour and adjacent non-neoplastic colon tissue samples" (page 6162, third full paragraph). The genes used in the study by Barrier et al are different from those claimed in the instant application (see entire document, especially page 6159). However, if with the use of a larger panel of genes and samples taken directly from the cancer lesion, Barrier concedes that the results of the study only "suggest the possibility to build an accurate prognosis predictor using gene expression profiles" and that the study "has to be confirmed by larger other studies" (see page 6162, first full paragraph).

Given the very large genus of biological samples and potential control samples encompassed by the rejected claims, and given the limited description provided by the prior art and specification with regard to the biological samples and controls capable of fulfilling the claim limitations of claims 49, 51-64, 79, and 81-88, the skilled artisan would not have been able to describe the broadly claimed genus of biological samples and controls that can be used in methods for management of colorectal cancer or colorectal polyps or discovery of therapeutic interventions therefor. Thus, there is no structural/functional basis provided by the prior art or instant specification for one of skill in the art to envision those

biological samples and controls that satisfy the functional limitations of the claims. Therefore, the skilled artisan would have reasonably concluded Applicant was not in possession of the claimed invention for claims 49, 51-64, 79, and 81-88.

Claims 49, 51-64, 79, and 81-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art, the amount of experimentation necessary and the relative skill levels of those in the art. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: The instant claims are drawn to a methods for measuring expression levels of polynucleotides from

biomarkers for colorectal cancer and colorectal polyps comprising the selection of a panel of biomarkers comprising SEQ ID NOs: 1, 2, 5, 15 and 16. The expression levels are quantified using cDNAs amplified with primers of SEQ ID NOs. 45-48, 53-54 and 73-76. Some claims are further limited to such methods wherein the expression levels of the biomarkers are compared to a control. Some claims are further limited to such methods wherein the comparison is used for the management of patient care (claims 57-58) or wherein the comparison is used for the discovery of therapeutic interventions of colorectal cancer and colorectal polyps (claim 59). Some claims are further drawn to such methods wherein the step of obtaining a sample of colorectal cells in minimally invasive. The instant claims are also drawn to kits for the determination of colorectal cancer (CRC) and colorectal polyps comprising SEQ ID NOs: 1, 2, 5, 15 and 16. Some kits further comprise SEQ ID NO:s 45-48, 53-54 and 7-76. The invention is complex in that it involves measuring a change in the level of RNA by amplification, such that either patient care can be managed or such that upon comparison with normal controls, the method can be used for discovery of therapeutic intervention. While not all the claims are directed toward such methods wherein the method is used for managed care or discovery of therapeutic

intervention, these are the only utilities disclosed in the specification. Thus the enablement rejection includes even those claimed methods that do not recite such limitations.

Breadth of the claims: The claims are extremely broad in that they encompass methods for measuring the expression levels of polynucleotides from any biological sample and comparing such expression levels to any control such that the comparison is used in any aspect of the management of patient care in colorectal cancer and colorectal polyps, or such that the comparison is used in the discovery of any therapeutic intervention of colorectal cancer and colorectal polyps. The large breadth of the claims exacerbates the complexity of the invention.

Guidance of the specification/The existence of working examples: The specification discloses the use of a mouse multiple intestinal neoplasia (MIN) model to determine expression differences between mouse MIN subjects comprising a chemically induced mutation in the APC gene and normal control littermates for which there was not aberration of the APC gene (page 5, paragraph 18). From these studies candidate genes were selected for study in human subjects; and from these studies with human samples, the disclosed panel of biomarkers was obtained (ibid). In one disclosed example, a panel of six

biomarkers is used "as the basis for determination of CRC in human subjects" -- although the biomarkers were applied to samples obtained from patients known to have CRC and from individuals independently validated as normal controls (page 8, paragraph 27). In another example, multiple biopsy samples taken from one exemplary patient diagnosed with CRC showed differences in expression of three biomarkers (see paragraph bridging pages 9 and 10). However, the specification gives no indication of what such a difference in expression means for patient care management or for the discovery of therapeutic interventions. In the last example, the specification teaches that multiple biopsies (again from a single patient), taken over a 53 cm region of the colon, where able to "distinguish differences in the colon tissue for the patient" whereas the same biopsy samples were rendered normal by conventional histological analysis. The specification teaches that such results demonstrate a minimally invasive swabbing collection method from an area distant from a cancerous lesion is capable of indicating a "non-normal colon condition" (page 10, paragraph 32).

The specification fails to teach how measurements of RNA expression can be used to manage patient care or to discover new therapeutic interventions.

The specification lacks a single example of the use of expression levels of SEQ ID NOs: 1, 2, 5, 15 and 16 in combination to manage patient care or to discover new inventions for CRC or colorectal polyps.

The specification does not teach what differences in expression of SEQ ID NOs: 1, 2, 5, 15 and 16 can be used in order to perform risk assessment, early diagnosis, establishing a prognosis, monitoring patient treatment or detecting relapse. For example, does a decrease in the level of SEQ ID NOs: 1, 2 and 5 indicate that a relapse is likely? How much of a decrease is required for such a conclusion to be reached? Furthermore, the specification teaches that "mRNA expression levels are not good predictors of protein expression levels, and that mRNA expression levels tell nothing of the post-translational modifications of proteins that are key to their biological activity" (page 7, paragraph 23). Along those same lines, the specification teaches that "in order to understand the expression levels of proteins, and their complete structure, the direct analysis of proteins is required" (ibid). In light of the admitted limitations of using RNA levels, how can such expression levels be used to manage patient care and or discover new interventions for CRC and/or colorectal polyps?

State of the prior art: The specification teaches that "given the complexity of biological systems, discovery of panels useful in providing value in patient care management for CRC is in the nascent stage" (page 5, paragraph 16). The prior art supports this statement. In post-filing art, Barrier et al (*Oncogene* 24:6155-6164, 2005; IDS Ref) teach the attempted construction of a prognosis predictor model for stage II and stage III colon cancer based on gene expression measurements that involve a number of genes, but which do not involve the claimed panel of biomarkers (see entire document, especially pages 6156-6158). However, Barrier concedes that the results of the study only "suggest the possibility to build an accurate prognosis predictor using gene expression profiles" and that the study "has to be confirmed by larger other studies" (see page 6162, first full paragraph). In other post-filing art, Hao et al (*Clinical Cancer Research* **11**:1400-1407, 2005; IDS Ref.) teach that gene expression of all five of the claimed sequences is altered in macroscopically normal colonic mucosa from individuals with a family history of sporadic colon cancer, but that prospective studies will be needed "to determine whether or not altered gene expression is associated with the subsequent development of adenomatous polyps and/or colonic carcinomas" (see entire document, especially the Abstract). Thus, the state

of the art is underdeveloped with respect to the use of a nucleic acids to diagnose and manage disorders in general; the state of the art is also underdeveloped with respect to the use of nucleic acids for the management of patient care and discovery of therapeutic interventions for CRC and colorectal polyps in particular.

Predictability of the art/Amount of experimentation necessary: The unpredictability of correlating gene expression level to any phenotypic quality is taught in the prior art by Wu (*J. Pathol.* **195**(1):53-65, 2001.). Wu teaches that gene expression data must be interpreted in the context of other biological knowledge, involving various types of "post genomics" informatics, including gene networks, gene pathways, and gene ontologies (page 53, left column). The reference indicates that many factors may be influential to the outcome of data analysis, and teaches that expression data can be interpreted in many ways. The conclusions that can be drawn from a given set of data depend heavily on the particular choice of data analysis. Much of the data analysis depends on such low-level considerations as normalization and such basic assumptions as normality (page 63 - Discussion). Additionally, post-filing art reveals that most gene association studies are typically wrong. Lucitini (*The Scientist*, page 20, Dec. 20, 2004) teaches that it

is strikingly common for follow-up studies to find gene-disease associations wrong (left column, 3rd paragraph). Lucitini teaches that two recent studies found that typically when a finding is first published linking a given gene to a disease there is only roughly a one-third chance that the study will reliably confirm the finding (left column, 3rd paragraph). Lucitini teaches that bigger sample sizes and more family-based studies, along with revised statistical methods should be included in the gene association studies (middle column, 1st full paragraph).

The lack of predictive success of gene expression studies may, in part, be due to the fact that increased mRNA is not always indicative of protein expression levels, as indicated in the specification (cited above). Chen et al (*Molecular and Cellular Proteomics* **1**:304-313, 2002) compared mRNA and protein expression for a cohort of genes in the same lung adenocarcinomas. Only 17% of 165 protein spots or 21% of the genes had a significant correlation between protein and mRNA expression levels. Chen et al clearly state that "the use of mRNA expression patterns by themselves, however, is insufficient for understanding the expression of protein products" (page 304) and "it is not possible to predict overall protein expression

levels based on average mRNA abundance in lung cancer samples" (pages 311-312).

Given the complex nature of the invention and the underdeveloped state of the art at the time of filing, there would be a large and prohibitive amount of experimentation required to make and use the claimed invention. Even for claims specifically reciting SEQ ID NOs: 1, 2, 5, 15 and 16 with particular samples from diseased tissue, one would have to establish that the differences in expression were statistically significant. This would include analysis of the different levels of expression in a large number of individuals first to establish what level of gene expression is considered "elevated" or "decreased" relative to a "normal" level of expression. One would then have to establish that elevated mRNA expression is correlated with 1) elevated protein expression and 2) the presence of a colorectal condition and perform studies that prove a correlation with the gene expression and a predisposition to development of the disease in the future.

Double Patenting

Claims 49, 51, 56—58, 60-64, 79, 81-83 and 88 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

claims 3-6, 10 and 14 of copending Application No. 11/242,111. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods comprising the steps of 1) obtaining a tissue sample by non-invasive or minimally invasive methods, 2) isolating RNA from the sample, 3) amplifying copies of cDNA from the isolated RNA, and 4) quantifying levels of cDNA amplified from the sample. Furthermore, both methods comprising the use of SEQ ID NOs: 1, 2, 5, and 15-16. Although the reference claims are slightly larger in scope in that they include the use of even more SEQ ID NOs as well as the early detection of Alzheimer's disease, ALS, prostate cancer, lung cancer and breast cancer, they encompass embodiments for colorectal cancer and for the elected SEQ ID NOs: in the instant invention. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the

Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

August 29, 2006

NANCY VOGEL
PRIMARY EXAMINER